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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,173	10/01/2003	Michael Hugh Quinn	CL/V-32421	6787

1095 7590 09/29/2005

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER
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CHEUNG, WILLIAM K

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/676,173

Applicant(s)

QUINN ET AL.

Examiner

William K. Cheung

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on September 16, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.53(d) based on parent Application No. 10/676173 is acceptable and a RCE has been established. An action on the RCE follows.
2. In view of amendment filed September 16, 2005, claim 2 has been cancelled. Claims 5, 6, 10-15 are drawn to non-elected subject matter. Claims 1, 3-4, 7-9 are examined with merit.

### ***Claim Objections***

3. Claims 3-4, 7-9 are objected to because of the following informalities: Claims 3-4, 7-9 are setting dependency onto claim 2 which has already been cancelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-4, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Müller (US Pat. 6,303,687).

The invention of claims 1, 3-4, 7-9 relates to a **polymerizable material** for making an ophthalmic device, comprising:

(a) a **water-soluble polyvinyl alcohol** having **crosslinkable groups**; and

(b) a **modifier** which is **different from but miscible with the water-soluble polyvinyl alcohol** and presented in the polymerizable material in an amount sufficient to improve one or more physical properties of the ophthalmic device made from the polymerizable material, wherein the one or more physical properties are selected from the group consisting of stress at break (N/mm<sup>2</sup>), percentage of elongation at break, toughness or energy to break (N.mm), and susceptibility to fracture, wherein the **modifier** is selected from the group consisting of **nanoparticles having a hydrophilic surface, a copolymer, a non-crosslinkable polyurethane, a crosslinkable polyurethane with vinyl group, and mixtures thereof**, wherein the **copolymer** is a copolymerization product of a mixture including at least one hydrophilic vinylic monomer

Art Unit: 1713

and at least one hydrophobic vinylic monomers, wherein the percentage of the hydrophobic units of the copolymer is sufficient high to impart at least one desired physical property to said ophthalmic device, wherein the at least one hydrophilic monomer is presented in the mixture sufficient to render the resultant copolymer miscible with the water-soluble polyvinyl alcohol.

The prior art to Müller relates to novel water-soluble crosslinkable polymers, in particular derivatives of a polyvinyl alcohol, which can be used to make contact lenses (Abstract). Müller further teaches the use of modifier units (column 5, line 52-54). The notion of using a hydrophobic vinylic comonomer or a mixture of a hydrophobic vinylic comonomer and a hydrophilic vinylic comonomer (modifier system) allowing the mechanical properties of the photocrosslinked polymer to be improved is expressly disclosed at column 14, line 10-15. Such mechanical properties are identified as freedom from stresses and tear strength at column 15, line 43-44, which appears to read on the instant claim 2.

As to Claims 3-4, Mülle's teaching of a derivative of a polyvinyl alcohol having a general formula of (I) at column 2, line 31-55, meets the elected PVA having formula (I) in the instant claim 3. The derivative of the polyvinyl alcohol having a molecular weight of at least about 2,000 which comprises from about 0.5 to about 80%, based on the number of hydroxyl groups in the polyvinyl alcohol, of units of the formula I is disclosed in Mülle's claim 1, column 24, claim 1. Müller also teaches that the radical  $R_2$  of his

Art Unit: 1713

formula I is a radical of the formula II at column 2, line 60, which meets the instantly claimed formula (IV) in Claim 4.

As to Claims 7-9, employing a small proportion of vinylpyrrolidone can be seen at column 11, line 1-7 and line 30.

Regarding the functionality of each of the claimed ingredients, in view of the substantially identical composition disclosed in Müller and the composition as claimed, the examiner has a reasonable basis that these claimed functionalities for the ophthalmic device application are inherently possessed in Müller.

In sum, all the limitations of Claims 1, 3-4, 7-9 are fully met by Müller's disclosure.

### ***Response to Arguments***

6. Applicant's arguments filed September 16, 2005 have been fully considered but they are not persuasive. Applicants argue that modifier units of Müller are incorporated into the composition of Müller as comonomers only. However, applicants fail to recognize that the modifier units of Müller can also be incorporated as a separate ingredient which meets the claim requirement of "different from" of claim 1. Applicants' attention is directed to Müller (col. 1, line 3-13; col. 10, line 47-58), the recitation "a

Art Unit: 1713

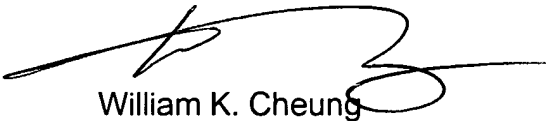
crosslinkable polymer or a crosslinkable polymer mixture comprising crosslinkable groups, acidic groups and/or basic groups", clearly indicates that the embodiment of the disclosed invention include the incorporation of the modifier as a separate ingredient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William K. Cheung

Primary Examiner

September 25, 2005

**WILLIAM K. CHEUNG  
PRIMARY EXAMINER**